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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/894,734	06/28/2001	Jack L. Leonard	07917-103001 / UMMC 99-45	9864

7590

11/14/2002

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EXAMINER

CROUCH, DEBORAH

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 11/14/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/894,734

Applicant(s)

LEONARD ET AL.

Examiner

Deborah Crouch, Ph.D.

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1049 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-49 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

The restriction election mailed October 9, 2002 is vacated. A new restriction/election appears below.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, drawn to methods of assaying the functionality of a translation product of a mutant Δ TRa2 gene in a cell comprising binding a labeled Δ TRa2 ligand to the translation product in a cell and measuring the amount, location or rate of transit of the ligand in the cell, classified in class 435, subclass 29.
- II. Claims 5, 10, 14 and 18, drawn to methods of identifying a candidate compound that modulates Δ TRa2 polypeptide activity contacting a Δ TRa2 polypeptide with a test compound and assaying for binding of the test compound to the Δ TRa2 polypeptide, classified in class 435, subclass 7.1.
- III. Claims 6, 11, 15 and 19, drawn to methods of methods of identifying a candidate compound that modulates Δ TRa2 polypeptide activity comprising contacting a Δ TRa2 polypeptide bound to a ligand with a test compound and measuring displacement of the Δ TRa2 ligand from the Δ TRa2, classified in class 435, subclass 7.1.
- IV. Claims 7, 8, 12, 16 and 20, drawn to methods of identifying a candidate compound that modulates Δ TRa2 polypeptide activity comprising incubating a test sample comprising an Δ TRa2 polypeptide with a test compound and assaying the test sample containing the test compound for an alteration in type II 5' deiodinase (D2) activity, classified in class 435, subclass 4.
- V. Claims 9, 13, 17 and 21, drawn to methods of identifying a candidate compound that modulates Δ TRa2 polypeptide activity comprising performing an actin binding assay with a test sample comprising an Δ TRa2 polypeptide and a test compound and determining p29 vesicle binding to F-actin, classified in class 435, subclass 7.1.
- VI. Claim 22, drawn to a compound that binds to a Δ TRa2 polypeptide, not classifiable.

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- VII. Claim 23, drawn to a compound that displaces a Δ TRa2 polypeptide ligand, not classifiable.
- VIII. Claim 24, drawn to a compound that alters II 5' deiodinase (D2) activity, not classifiable.
- IX. Claim 25, drawn to a compound that alters the binding of p29 vesicles to F-actin, not classifiable.
- X. Claims 26 and 27, drawn to methods of treating a subject who has a neurological disorder comprising administering to the subject a Δ TRa2 ligand, classified in class 514, subclass 1.
- XI. Claims 28-49, drawn to a nucleic acid molecule comprising a Δ TRa2 targeting construct, a vector comprising the construct, a transgenic nonhuman animal whose germ cells and somatic cells comprise a mutated TRa gene wherein the binding of thyroxine (T4) to Δ TRa2 polypeptide is inhibited, classified in class 800, subclass 13.

The inventions are distinct, each from the other because:

Inventions I-V are mutually exclusive and independent methods of assay. Each method of assay requires materially different and separate assay steps from the other methods of assay. Further, none of the methods of assay are required to implement any of the other methods of assay.

Inventions VI-IX are mutually exclusive and independent compounds as they are not classifiable and thus cannot be searched.

Inventions I-V and inventions VI-IX are mutually exclusive and independent. As the compounds cannot be classified, their relationship to the methods of assay cannot be determined.

Inventions I-V and invention X are mutually exclusive methods. Inventions I-V are in vitro assays to determine a compound's effect on Δ TRa2 polypeptide activity. Invention X is to a method of treatment comprising administering a Δ TRa2 ligand. None of inventions I-V are required for the implementation of invention X.

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Inventions VI-IX and invention X are mutually exclusive methods. Inventions VI-IX are to compounds. Invention X is to a method of treatment comprising administering a Δ TRa2 ligand. None of inventions VI-IX are required for the implementation of invention X.

Inventions I-X and XI are mutually exclusive and independent. None of the methods of assay, compounds or method of treatment of inventions I-X are required for the implementation of the transgenic nonhuman animal of invention XI.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is (703) 308-1126. The examiner's SPE is Deborah Reynolds, whose telephone number is (703) 305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Art Unit LIE, Ms. Dianiece Jacobs, whose telephone number is (703) 305-3388.

The fax number is (703) 308-4242.

Dr. D. Crouch
November 8, 2002

Deborah Crouch
DEBORAH CROUCH
PRIMARY EXAMINER
GROUP 1800-1630